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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,923	10/30/2000	David H. Lynch	2836-E	8828

7590 06/25/2002

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	11

DATE MAILED: 06/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/699923	LYNCH ET AL
	Examiner	Art Unit
	GAMBEL	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4/9/01

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 12, 13, 15-35

4a) Of the above claim(s) _____ is/are withdrawn from consideration. 12, 13, 17-22, 26-28, 33-35

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 15, 16, 23-25, 29-32, 36

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☑ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

1. Applicant's election without traverse of Group II (claims 15-16, 23-36) and the species GM-CSF in Paper No. 10 is acknowledged.

Claims 15,16, 23-25, 29-32 and 36 are being acted upon as the elected invention / species.

Claims 12-13,17-22, 26-28 and 33-35 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species.

Claims 1-11 and 14 have been canceled previously.

2. Applicant should amend the first line of the specification to update the status of the priority documents. USSNs 08/725,540 and 08/5390,142 are now abandoned.

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected. Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
Appropriate corrections are required

4. The filing date of the instant claims as it reads on the elected invention and species is deemed to be the filing date of parent application USSN 08/539,142, filed 10/4/95. However, it is noted that the priority of the non-elected species CD40L and anti-CD40 antibodies appears to be parent application USSN 09/154,903, filed 9/17/98.

If applicant desires priority other than that indicated herein, applicant is invited to point out and provide documentary support for the priority of the instant claims. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined *under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 15,16, 23-25, 29-32 and 36 are rejected under 35 U.S.C. § 102(e) as being anticipated by Galy et al. (U.S. Patent No. 6,015,554) (see entire document).

Galy et al. teach methods of inducing $CD34^+$ progenitor and stem cell populations into dendritic cells capable of dendritic functional activities including antigen-presenting ability (e.g. columns 7-8, overlapping paragraph) including loading cells with antigen (column 11, paragraph 1) (e.g., see Detailed Description of the Invention, including columns 7-11, Examples 1-3, 8). Example 8 on columns 27-28 provides for the differentiative potential of $CD34^+$ progenitor populations with cytokines including FLT3 ligand and GM-CSF into cells with the morphological and immunophenotypic features associated with dendritic cells. Although Galy et al. Does not explicitly indicate that the FLT3 ligand was recombinantly made, the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. Also, the ordinary artisan would have immediately envisaged the use of recombinant cytokines or molecules such as FLT3 ligand at the time the invention was made, given the standard and convenient use of homogeneous recombinant molecules at the time the invention was made by the ordinary artisan. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to produce dendritic cells from $CD34^+$ progenitor and stem cell populations in the presence of FLT3 ligand and GM-CSF and the referenced use of dendritic cells to present antigen.

8. Claims 15,16, 23-25, 29-32 and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Galy et al. (U.S. Patent No. 6,015,554) in view of Steinman et al. (U.S. Patent No. 5,994,126).

Galy et al. teach methods of inducing $CD34^+$ progenitor and stem cell populations into dendritic cells capable of dendritic functional activities including antigen-presenting ability (e.g. columns 7-8, overlapping paragraph) including loading cells with antigen (column 11, paragraph 1) (e.g., see Detailed Description of the Invention, including columns 7-11, Examples 1-3, 8). Example 8 on columns 27-28 provides for the differentiative potential of $CD34^+$ progenitor populations with cytokines including FLT3 ligand and GM-CSF into cells with the morphological and immunophenotypic features associated with dendritic cells. Although

Galy et al. does not explicitly indicate that the FLT3 ligand was recombinantly made, the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. Also, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ recombinant cytokines or molecules such as FLT3 ligand at the time the invention was made, given the standard and convenient use of homogeneous recombinant molecules at the time the invention was made by the ordinary artisan

The Examples (e.g. Example 8) in Galy et al. do no explicitly expose the $CD34^+$ progenitor and stem cell populations into dendritic cells incubated with cytokines including FLT3 ligand and GM-CSF with antigen to process and express antigen per se.

In addition to the to art known teaching of dendritic functional activities including antigen-presenting ability (e.g. columns 7-8, overlapping paragraph) including loading cells with antigen (column 11, paragraph 1) (e.g., see Detailed Description of the Invention, including columns 7-11, Examples 1-3, 8) referenced by Galy et al., Steinman et al. also teach the art known exposure of dendritic cells to antigen in order to process and express antigen (see entire document)

Steinman et al. teach producing dendritic cell precursors, including $CD34^+$ precursors, which mature into mature dendritic cell populations including pulsing said dendritic cells with antigen as well as their expansion by a number of cytokines, including GM-CSF for various immunological interventions (see entire document, including Summary of the Invention; Detailed Description of the Invention, columns 12-51).

One of ordinary skill in the art at the time the invention was made would have been motivated to expose $CD34^+$ progenitor and stem cell populations into dendritic cells incubated with cytokines including FLT3 ligand and GM-CSF with antigen to process and express antigen for various immunological procedures and interventions, known and practiced with dendritic cells at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. Claims 15,16, 23-25, 29-32 and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinman et al. (U.S. Patent No. 5,994,126) in view of
Lyman et al. (U.S. Patent No. 5,554,512; 1449) AND Inaba et al. (PNAS 90: 3038-3042, 1993; 1449).

Steinman et al. teach producing dendritic cell precursors, including $CD34^+$ precursors, which mature into mature dendritic cell populations including pulsing said dendritic cells with antigen as well as their expansion by a number of cytokines, including GM-CSF for various immunological interventions (see entire document, including Summary of the Invention; Detailed Description of the Invention, columns 12-51).

Steinman et al. differs from the claimed invention by not disclosing FLT3-ligand per se in expanding dendritic cell populations.

Lyman et al. teach the use of FLT3-ligand, including recombinant FLT3 ligand, alone or in combination with other cytokines encompassed by the claimed invention to stimulate the proliferation of hemopoietic and non-hemopoietic stem cells (see entire document, columns 6-7). Lyman et al. differ from the claimed invention, by not teaching that dendritic themselves are conducive to FLT3-ligand stimulation.

Inaba et al. teach the granulocytes, macrophages and dendritic cells arise from a common hemopoietic progenitor, wherein said progenitor are stimulated by cytokines such as GM-CSF (see entire document, including Abstract, Introduction). Given that dendritic cells have a common stem cell with other hemopoietic progenitors/stem cells and the cytokines such as GM-CSF provided stimulatory activity to such stem/dendritic cells; the provision of FLT3-ligand and GM-CSF would have been expected to provide stimulatory activity of various hemopoietic cells, including dendritic cells at the time the invention was made.

One of ordinary skill in the art at the time the invention was made would have been motivated to expose $CD34^+$ progenitor and stem cell populations into dendritic cells incubated with cytokines including FLT3 ligand and GM-CSF with antigen to process and express antigen for various immunological procedures and interventions, known and practiced with dendritic cells at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel

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June 27, 2002